K002443

OCT 1 8 2000

15. 510(k) Summary

Submitted By:
OASIS Research, LLC
514 South Vermont Avenue
Glendora, CA 91741

Contact:
Norman Delgado, President
(626) 914-2891

Device Classification:

Trade Name:	Collagen Wound Dressing
Common/Usual Name:	Topical Wound Dressing
Classification Name:	Dressing, Wound
Classification Number:	79 KMF
Regulatory Class:	Class II

Statement of Substantial Equivalence:
The proposed device, Collagen Wound Dressing, is similar to predicate collagen-based wound dressings that are currently marketed for the management of wounds including the SIS Wound Dressing II (K993948) manufactured by Cook Biotech, the Fibracol* Plus Collagen Wound Dressing with Alginate (K982597) manufactured by Johnson & Johnson Medical, and the SkinTemp® Kollagen Wound Management Material (K913023) and Medifil® Kollagen Particles (K910944) manufactured by Biocore Medical Technologies.

The Collagen Wound Dressing is similar with respect to indications for use, materials, and physical construction to predicate devices in terms of section 510(k) substantial equivalency.

Intended Use:
The Collagen Wound Dressing is intended for the management of wounds including full thickness and partial thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, second-degree burns, donor sites and other bleeding surface wounds, abrasions, traumatic wounds healing by secondary intention, dehisced surgical incisions.

The device is intended for one-time use.

Device Description:
Collagen Wound Dressing is a wound care dressing composed of hydrolyzed bovine collagen. It is a soft, absorbent, topical wound dressing supplied in sheet form. Collagen Wound Dressing maintains a physiologically moist microenvironment at the wound surface.

Biocompatibility:

The following safety testing has been conducted to support the biocompatibility of this product. Collagen Wound Dressing has passed the requirements of all tests and has been shown to be a safe topical wound dressing.

Cytotoxicity - Agarose Overlay (L929 Cells)
Acute Systemic Toxicity (Mice)
Intracutaneous Toxicity (Rabbits)
Acute Oral Toxicity (Mice)
Muscle Implantation (Rabbits – 7 days)
In-Vitro Hemolysis (Rabbit RBCs)
Dermal Sensitization – Maximization (Guinea Pigs)
Systemic Antigenicity (Guinea Pigs)
Skin Irritation (Rabbits)
Ocular Irritation (Rabbits)
USP Rabbit Pyrogen (Rabbits)
Limulus Amebocyte Lysate Chromogenic Assay

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Mr. James Christensen
Oasis Research, LLC
514 S. Vermont Avenue
Glendora, California 91741

Re: K002443
Trade Name: Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: August 7, 2000
Received: August 9, 2000

Dear Mr. Christensen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

16. Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K002443

Device Name: Collagen Wound Dressing

Indications for Use:

INDICATIONS:
Collagen Wound Dressing is indicated for the management of wounds including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

PRECAUTIONS:
Collagen Wound Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause. Collagen Wound Dressing may be used under compression therapy with healthcare professional supervision.

CONTRAINDICATIONS:
Collagen Wound Dressing is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to collagen.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002443

Prescription Use X OR Over-The-Counter Use